

10-01-04

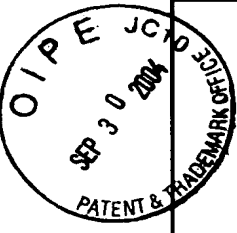
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PTO/SB/21 (04-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

|   |                             |                  |
|---|-----------------------------|------------------|
| <b>Application Number</b>                       | 10/049,321                  |                  |
|   | <b>Filing Date</b>          | July 28, 2000    |
|   | <b>First Named Inventor</b> | Ian G. Charles   |
|   | <b>Art Unit</b>             | N/A              |
|   | <b>Examiner Name</b>        | Not Yet Assigned |
| <b>Attorney Docket Number</b>                   | HO-P02379US0                |                  |
| <b>Total Number of Pages in This Submission</b> |                             |                  |

## ENCLOSURES (Check all that apply)

|  |   |   |
|--|---|---|
| <input checked="" type="checkbox"/> Fee Transmittal Form                     | <input type="checkbox"/> Drawing(s)   | <input type="checkbox"/> After Allowance communication to Technology Center (TC)        |
| <input checked="" type="checkbox"/> Fee Attached                             | <input type="checkbox"/> Licensing-related Papers                                       | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Amendment/Reply                                     | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final   | <input type="checkbox"/> Petition to Convert to a Provisional Application               | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declaration(s)                           | <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request                           | <input type="checkbox"/> Terminal Disclaimer  | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
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| <input checked="" type="checkbox"/> Information Disclosure Statement         | <input type="checkbox"/> CD, Number of CD(s) _____                                      | 23 References   |
| <input type="checkbox"/> Certified Copy of Priority Document(s)              | <b>Remarks</b>  |   |
| <input type="checkbox"/> Response to Missing Parts/Incomplete Application    |   |   |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 |   |   |

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

|                                |   |
|--------------------------------|---|
| <b>Firm or Individual name</b> | FULBRIGHT & JAWORSKI L.L.P.<br>Melissa W. Acosta - 45,872 |
| <b>Signature</b>               |   |
| <b>Date</b>                    | September 30, 2004  |

### Transmittal

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. ER 147056380 US, in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: September 30, 2004

Signature:

(Annette Devereux)

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**FEE TRANSMITTAL  
for FY 2004**

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 180.00**Complete if Known**

|                      |                  |
|----------------------|------------------|
| Application Number   | 10/049,321       |
| Filing Date          | July 28, 2000    |
| First Named Inventor | Ian G. Charles   |
| Examiner Name        | Not Yet Assigned |
| Art Unit             | N/A              |
| Attorney Docket No.  | HO-P02379US0     |

**METHOD OF PAYMENT (check all that apply)**
☐ Check ☐ Credit Card ☐ Money Order ☐ Other ☐ None
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Deposit  
Account  
Name

Fulbright &amp; Jaworski L.L.P.

**The Director is authorized to:** (check all that apply)☐ Charge fee(s) indicated below ☒ Credit any overpayments☒ Charge any additional fee(s) or any underpayment of fee(s)☐ Charge fee(s) indicated below, except for the filing fee  
to the above-identified deposit account.**FEE CALCULATION****1. BASIC FILING FEE**

| Large Entity |          | Small Entity |          | Fee Description        | Fee Paid |
|--------------|----------|--------------|----------|------------------------|----------|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |                        |          |
| 1001         | 770      | 2001         | 385      | Utility filing fee     |          |
| 1002         | 340      | 2002         | 170      | Design filing fee      |          |
| 1003         | 530      | 2003         | 265      | Plant filing fee       |          |
| 1004         | 770      | 2004         | 385      | Reissue filing fee     |          |
| 1005         | 160      | 2005         | 80       | Provisional filing fee |          |

**SUBTOTAL (1)** (\$) 0.00**2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE**

| Total Claims       | Extra Claims | Fee from below | Fee Paid |
|--------------------|--------------|----------------|----------|
| Independent Claims | ** =         | x              | =        |
| Multiple Dependent | ** =         | x              | =        |

| Large Entity |          | Small Entity |          | Fee Description  | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |  |          |
| 1202         | 18       | 2202         | 9        | Claims in excess of 20                                     |          |
| 1201         | 86       | 2201         | 43       | Independent claims in excess of 3                          |          |
| 1203         | 290      | 2203         | 145      | Multiple dependent claim, if not paid                      |          |
| 1204         | 86       | 2204         | 43       | ** Reissue independent claims over original patent         |          |
| 1205         | 18       | 2205         | 9        | ** Reissue claims in excess of 20 and over original patent |          |

**SUBTOTAL (2)** (\$) 0.00

\*\*or number previously paid, if greater; For Reissues, see above

**FEE CALCULATION (continued)****3. ADDITIONAL FEES**

| Large Entity |          | Small Entity |          | Fee Description  | Fee Paid |
|--------------|----------|--------------|----------|--|----------|
| Fee Code     | Fee (\$) | Fee Code     | Fee (\$) |  |          |
| 1051         | 130      | 2051         | 65       | Surcharge - late filing fee or oath  |          |
| 1052         | 50       | 2052         | 25       | Surcharge - late provisional filing fee or cover sheet.                    |          |
| 1053         | 130      | 1053         | 130      | Non-English specification  |          |
| 1812         | 2,520    | 1812         | 2,520    | For filing a request for <i>ex parte</i> reexamination                     |          |
| 1804         | 920*     | 1804         | 920*     | Requesting publication of SIR prior to Examiner action                     |          |
| 1805         | 1,840*   | 1805         | 1,840*   | Requesting publication of SIR after Examiner action                        |          |
| 1251         | 110      | 2251         | 55       | Extension for reply within first month                                     |          |
| 1252         | 420      | 2252         | 210      | Extension for reply within second month                                    |          |
| 1253         | 950      | 2253         | 475      | Extension for reply within third month                                     |          |
| 1254         | 1,480    | 2254         | 740      | Extension for reply within fourth month                                    |          |
| 1255         | 2,010    | 2255         | 1,005    | Extension for reply within fifth month                                     |          |
| 1401         | 330      | 2401         | 165      | Notice of Appeal   |          |
| 1402         | 330      | 2402         | 165      | Filing a brief in support of an appeal                                     |          |
| 1403         | 290      | 2403         | 145      | Request for oral hearing   |          |
| 1451         | 1,510    | 1451         | 1,510    | Petition to institute a public use proceeding                              |          |
| 1452         | 110      | 2452         | 55       | Petition to revive - unavoidable   |          |
| 1453         | 1,330    | 2453         | 665      | Petition to revive - unintentional   |          |
| 1501         | 1,330    | 2501         | 665      | Utility issue fee (or reissue)   |          |
| 1502         | 480      | 2502         | 240      | Design issue fee   |          |
| 1503         | 640      | 2503         | 320      | Plant issue fee  |          |
| 1460         | 130      | 1460         | 130      | Petitions to the Commissioner  |          |
| 1807         | 50       | 1807         | 50       | Processing fee under 37 CFR 1.17(q)  |          |
| 1806         | 180      | 1806         | 180      | Submission of Information Disclosure Stmt                                  | 180.00   |
| 8021         | 40       | 8021         | 40       | Recording each patent assignment per property (times number of properties) |          |
| 1809         | 770      | 2809         | 385      | Filing a submission after final rejection (37 CFR 1.129(a))                |          |
| 1810         | 770      | 2810         | 385      | For each additional invention to be examined (37CFR 1.129(b))              |          |
| 1801         | 770      | 2801         | 385      | Request for Continued Examination (RCE)                                    |          |
| 1802         | 900      | 1802         | 900      | Request for expedited examination of a design application                  |          |

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

**SUBTOTAL (3)** (\$) 180.00**SUBMITTED BY**

Name (Print/Type) Melissa W. Acosta

Registration No.  
(Attorney/Agent)

45,872

(Complete (if applicable))

Telephone (713) 651-5407

Signature

Date

September 30, 2004

**Fee Transmittal**

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Dated: September 30, 2004

Signature:

*Annette Devereux*

(Annette Devereux)

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Dated: September 30, 2004 Signature: *Annette Devereux*

(Annette Devereux)

Docket No.: HO-P02379US0  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Ian G. Charles et al.

Application No.: 10/049,321

Confirmation No.:

Filed: July 28, 2000

Art Unit: N/A

For: MICROENCAPSULATED NITRIC OXIDE  
SYNTHASE SOURCE

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement is filed more than three months after the U.S. filing date, OR more than three months after the date of entry of the national stage of a PCT application, AND after the mailing date of the first Office Action on the merits, whichever occurs first, but before the mailing date of a Final Office Action or Notice of Allowance (37 CFR 1.97(c)).

A copy of each required reference on the PTO/SB/08 is attached.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an

admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

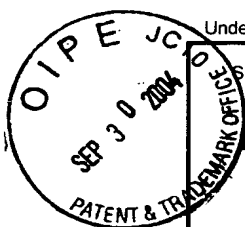
Please charge our Deposit Account No. 06-2375 in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p). The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 06-2375, under Order No. HO-P02379US0. A duplicate copy of this paper is enclosed.

Dated: September 30, 2004

Respectfully submitted,



By  
Melissa W. Acosta  
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PTO/SB/08A (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U. S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(use as many sheets as necessary)</i> |   |    |   | <b>Application Number</b>     | 10/049,321       |
|  |   |    |   | <b>Filing Date</b>            | July 28, 2000    |
|  |   |    |   | <b>First Named Inventor</b>   | Ian G. Charles   |
|  |   |    |   | <b>Art Unit</b>               | N/A              |
|  |   |    |   | <b>Examiner Name</b>          | Not Yet Assigned |
| <b>Sheet</b>   | 1 | of | 2 | <b>Attorney Docket Number</b> | HO-P02379US0     |

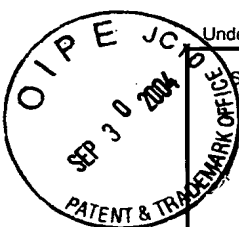
| U.S. PATENT DOCUMENTS |                       |   |                                |  |  |
|-----------------------|-----------------------|---|--------------------------------|--|--|
| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number<br>Number-Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant<br>of Cited Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|                       | AA                    | US-5,800,829  | 09-01-1998                     | Dionne, et al.                                     |  |
|                       | AB                    | US-5,908,756  | 06-01-1999                     | Snyder, et al.                                     |  |
|                       | AC                    | US-5,840,521  | 11-24-1998                     | Barth  |  |
|                       | AD                    | US-5,654,168  | 08-05-1997                     | Bujard, et al.                                     |  |
|                       | AE                    | US-5,922,927  | 07-13-1999                     | Bujard, et al.                                     |  |
|                       | AF                    | US-5,759,836  | 06-02-1998                     | Amin, et al.                                       |  |

| FOREIGN PATENT DOCUMENTS |                       |                           |  |                                |   |  |
|--------------------------|-----------------------|---------------------------|--|--------------------------------|---|--|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |  | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document                      | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear |
|                          |                       | Country Code <sup>3</sup> | Number <sup>4</sup> -Kind Code <sup>5</sup> (if known) |                                |   |  |
|                          | BA                    | WO                        | 9900510  | 01-07-1999                     | Brigham and Women's Hospital  |  |
|                          | BB                    | WO                        | 0109307  | 02-08-2001                     | University College London   |  |
|                          | BC                    | WO                        | 9802555  | 01-22-1889                     | Salerno, John C.  |  |
|                          | BD                    | WO                        | 0109375  | 02-08-2001                     | University College London   |  |
|                          | BE                    | WO                        | 9933971  | 07-08-1999                     | Medical College of Georgia Research Institute, Inc.                     |  |
|                          | BF                    | WO                        | 9911620  | 03-11-1999                     | Pfizer Products Inc.  |  |
|                          | BG                    | WO                        | 9826066  | 06-18-1998                     | Cerasoli, Franklin, Jr.   |  |
|                          | BH                    | WO                        | 9958155  | 11-18-1999                     | The Salk Institute For Biological Studies                               |  |
|                          | BI                    | WO                        | 9600006  | 01-04-1996                     | University of Pittsburgh of the Commonwealth System of Higher Education |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

| NON PATENT LITERATURE DOCUMENTS |                       |  |                |
|---------------------------------|-----------------------|--|----------------|
| Examiner Initials               | Cite No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|                                 | CA                    | Read, Tracy-Ann, et al. Cells Encapsulated in Alginate: A Potential System For Delivery of Recombinant Proteins to Malignant Brain Tumors., Int. J. Devl Neuroscience, Vol. 17, 653-663, 1999.   |                |
|                                 | CB                    | No et al., Ecdysone-inducible gene expression in mammalian cells and transgenic mice., Proc. Natl. Acad. Sci. USA 93, 3346-3351, 1996.   |                |
|                                 | CC                    | Yoshio et al., A phosphatidylinositol 3-kinase inhibitor wortmannin induces radioresistant DNA synthesis and sensitizes cells to bleomycin and ionizing radiation., International Journal of Cancer, Vol 78, 642-647, Nov. 23, 1998.                           |                |
|                                 | CD                    | Daniel, Rene et al., A Role for DNA-PK in Retroviral DNA Integration, Science, Vol. 284, 644-647, 1999.  |                |
|                                 | CE                    | Kawaguchi et al., In Vivo Gene Transfection of Human Endothelial Cell Nitric Oxide Synthase  |                |
| <b>Examiner Signature</b>       |                       | <b>Date Considered</b>   |                |



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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 2 of 2

**Complete if Known**

|                        |                  |
|------------------------|------------------|
| Application Number     | 10/049,321       |
| Filing Date            | July 28, 2000    |
| First Named Inventor   | Ian G. Charles   |
| Art Unit               | N/A              |
| Examiner Name          | Not Yet Assigned |
| Attorney Docket Number | HO-P02379US0     |

|  |    |  |  |
|--|----|--|--|
|  |    | in Cardiomyocytes Causes Apoptosis -Like Cell Death., Circulation, Vol. 95, 2441-2447, 1997.   |  |
|  | CF | Chen et al., Expression and Function of Recombinant Endothelial Nitric Oxide Synthase Gene in Canine Basilar Artery, Circ. Res. Vol. 80, 327-335, 1997.  |  |
|  | CG | Amin et al., A novel mechanism of action of tetracyclines: Effects on nitric oxide synthases., Proc. Natl. Acad. Sci. USA, Vol.93, 14014-14019, 1996.  |  |
|  | CH | Christodouloupoulos, Garyfallia, et al., Potentiation of Chlorambucil Cytotoxicity in B-Cell Chronic Lymphocytic Leukemia by Inhibition of DNA-dependent Protein Kinase Activity sing Wortmannin, Cancer Research 58, 1789-1792, 1998. |  |
|  | CI | Xie et al., Transfection with the Inducible Nitric Oxide Synthase Gene Suppresses Tumorigenicity and Abrogates Metastasis by K-1735 Murine Melanoma Cells., J. Exp. Med. Vol. 181, 1333-1343, 1995.                                    |  |
|  | CJ | Kullo et al., Expression and Function of recombinant Endothelial NO Synthase in Coronary Artery Smooth Muscle Cells., Arterio. Thromb. Vasc. Biol. 17, 2405-2412, 1997.  |  |
|  | CK | Del Real, Gustavo, et al., Suppression of HIV-1 infection in linomide-treated SCID-hu-PBL mice., AIDS(London), Vol. 12, 865-872, May, 28, 1998.  |  |
|  | CL | Invitrogen, "Ecdysone-Inducible Mamalian Expression System: An Inducible Gene Expression System for Mammalian Cells Utilizing the Ecdysone Analog Ponasterone A., Version E, 1998-2000   |  |
|  | CM | Invitrogen, T-Rex System: A Tetracycline-regulated Expresson System for Mammalian Cells., Version D, 1999-2000.  |  |
|  | CN | Iwashina et al, "Transfection of Inducible Nitric Oxide Synthase Gene Causes Apoptosis in Vascular Smooth Muscle Cells," Circulation Vol. 98, 1998, pgs. 1212-1218.  |  |

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

|                       |  |                    |  |
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| Examiner<br>Signature |  | Date<br>Considered |  |
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Application No. (if known): 10/049,321

Attorney Docket No.: HO-P02379US0

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IDS (Citation) by Applicant

